

REMARKS

Claims 1-88 are pending in the application. In the Final Office Action Summary sheet, it was indicated that claims 1-12, 18-20, 22-23, 25-43, 46-50, 65-75, and 77-78 stand rejected; claims 13-17, 21, 24, 44, 45, 76, and 79-88 were objected to, but were indicated to be allowable if amended to incorporate the base claim from which each depends and any intervening claims; and claims 51-64 were allowed. Reconsideration and Allowance of the present application in view of the remarks that follow is respectfully requested.

Numerous inconsistencies in the Final Office Action have been noted. Claim 14 is an independent claim and was indicated as allowable, but objected for depending from a rejected base claim. However, claim 14 is a base claim, and withdrawal of the objection thereto is respectfully requested. Furthermore, claims 18, 19, 20, which depend from claim 14, were indicated as being rejected over the combination of EP Publication No. 0 867 149 A1 to Jobe and U.S. Patent No. 6,306,139 to Fuentes. This is not possible since, if claim 14 is allowable, the claims depending from it must also be allowable. Accordingly, it is respectfully submitted that claims 18, 19 and 20 are also allowable, and withdrawal of the rejection of the same is respectfully requested.

Also, claim 27 was indicated as being rejected in the Office Action Summary. In reviewing the Office Action, however, none of the cited references were applied to claim 27. It is not clear from the Office Action what the basis for the rejection of claim 27 is.

In addition, claim 65 was indicated in the Office Action Summary as being rejected; however, the Office Action does not apply to any of the references to claim 65, and it is therefore not clear the basis for the rejection of claim 65. In addition, as indicated in the First Office Action Response, claim 65 presents original claim 24 in independent form. Claim 24 was indicated as allowable in the First Office Action and in the Final Office Action. Accordingly, since claim 65 and its dependent claim 66 are allowable, withdrawal of the rejection of the same is respectfully requested.

Also, claim 67 was indicated in the Office Action as being rejected over the combination of Jobe and Fuentes. As indicated in the First Office Action Response,

claim 67 presents original claim 45 in independent form. Claim 45 was indicated as allowable in the First Office Action and in the Final Office Action. Accordingly, claim 67 and its dependent claims 68-78 are allowable, and withdrawal of the rejection of the same is respectfully requested.

Further, claims 79-88 were indicated to be allowable but objected to as being dependent upon a rejected base claim. However, claim 79 is a base claim, and claims 80-88 depend directly or indirectly from it. Accordingly, withdrawal of the objection to claims 79-88 is respectfully requested.

In the Final Office Action, claims 1, 3, 7, 22, 26, 33-34, 37 40, and 46 were rejected under 35 U.S.C. § 102(b) as being anticipated by EP Publication No. 0 867 149 A1 to Jobe. It is respectfully submitted that Jobe does not anticipate the claims for at least the reasons that follow, and withdrawal of this basis of the rejection is respectfully requested.

Claim 1 recites “a plate having a generally triangular shape and having an upper node and a pair of lower nodes; an upper hole in the plate at the upper node to receive a screw for passage into an L5 vertebra; and a first lower hole in the plate formed through one of the lower nodes to receive a screw for passage into the S1 vertebra and a second lower hole in the plate through the other of the lower nodes to receive a screw for passage into the S1 vertebra, wherein said plate includes a profile along said upper node and said pair of lower nodes adapted to conform to the anterior margin of at least one of the L5 and S1 vertebrae.” In order for a reference to anticipate a claim, it is necessary for the reference to teach or disclose each element, either expressly or inherently, of the claimed invention “arranged as in the claim.” Lindermann Maschinenfabrik GmbH v. American Hoist and Derrick Co., 221 USPQ 481, 485 (Fed. Cir. 1984.) Jobe does not expressly disclose the elements arranged as in claim 1. The office action asserts that post devices 14a, 14b, and 14c “are capable of being positioned through the plate into the L5 and S1 vertebrae” since Jobe discloses “the shape size and thickness of plate member 12 is subject to considerable modification depending upon the location of bone sections 6 and 7.” However, Jobe provides no express disclosure or teaching of how the plate could be modified for anterior placement on L5-S1 with the elements arranged as in claim 1. It is respectfully submitted that a fair reading of

Jobe in its entirety finds no basis for the assertion that it is capable of being modified for the anterior placement on L5-S1. As discussed in Jobe, the bone portions 6 and 7 are preferably “bones which are subjected primarily to forces parallel to the bone surface, such as those which tend to separate the bone sections or cause lateral movement of the bone sections.” *See* col. 4, lines 49-54. Such bones are generally “isolated from forces transverse to the bone surface and are not required to carry a significant load. Examples of such bones include facial and cranial bones, although it would be understood that use of the bone fixation apparatus may also be used with other **suitable** bones.” (Emphasis added.) *See* col. 4, line 54 to col. 5 line 1. Accordingly, Jobe only discloses modifying the plate for suitable bones, i.e. bones that do not carry significant load, that are isolated from transverse forces, and subject primarily to forces parallel to the surface of the bone. The plate in claim 1, however, is adapted to conform to the anterior margin of at least one of the L5 and S1 vertebrae. The plate is thus subject to substantial loading, including the weight supported by the spinal column, and is also subject to loading transverse to the vertebrae since the plate is adapted to extend across a joint that rotates and flexes, i.e. the spinal disc space extending between L5 and S1. Accordingly, Jobe only make a general reference that the plate is capable of being modified, and, when this reference is viewed in its entirety, it is revealed that Jobe does not expressly disclose modifying the triangular plate element 12 for connection to the L5 and S1 vertebrae.

Jobe also does not inherently disclose a plate with the arrangement of elements recited in claim 1. It has been held with regard to anticipation that “[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Oelrich*, 212 USPQ 323, 326 (C.C.P.A. 1981)(quoting *Hansgirk v. Kemmer*, 26 CCPA 937, 940 (1939). Also, “when the reference is silent about the asserted inherent characteristics, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill.” *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). The arrangement of elements in claim 1 not expressly disclosed in Jobe also do not necessarily result from Jobe. For

example, since Jobe only describes the plate as being useful extending between bone sections 6 and 7 having the loading characteristics discussed above, one skilled in the art would not seek to modify Jobe for anterior placement on L5-S1 since it would not be considered to be “suitable bones” as defined in Jobe. In In re Robertson, 169 F. 3d 743 (Fed. Cir. 1999), the Federal Circuit reversed a finding of anticipation when the prior art was only capable of being modified and one of ordinary skill in the art would not have recognized the modification being claimed. In order to modify Jobe to arrive at the elements arranged in claim 1, it is submitted that it is necessary to rely on Applicants disclosure, which is not proper. Accordingly, Jobe does not anticipate claim 1, and withdrawal of the rejection of claim 1 is respectfully requested.

Claims 3 and 7 depend from claim 1 and are allowable at least for the reasons provided above and for other reasons. For example, claim 3 recites that the plate “includes at least one spike extending from a posterior face of said plate positionable into the L5 vertebra.” Jobe discloses a longitudinal flange or rib 30, but does not disclose a spike positionable in the L5 vertebra. Accordingly, withdrawal of the rejection of claims 3 and 7 is respectfully requested.

Claim 22 recites “a plate having a generally triangular shape with an upper node positionable along an upper vertebra and a pair of lower nodes positionable along a lower vertebra; an upper hole in the plate at the upper node to receive a screw for engaging the upper vertebra; a first lower hole in the plate through one of the lower nodes to receive a screw for engaging the lower vertebra and a second lower hole in the plate through the other of the lower nodes to receive a screw for engaging the lower vertebra, wherein said upper hole extends through said plate along an axis oriented away from said pair of lower nodes.” Jobe, in contrast and as discussed above with respect to claim 1, does not expressly or inherently disclose the elements arranged as in claim 22 since claim 22 claims a plate arranged to extend between an upper vertebra and a lower vertebra. Accordingly, claim 22 distinguishes Jobe, and withdrawal of this basis of the rejection is respectfully requested.

Claim 26 depends from claim 22 and was also rejected as being anticipated by Jobe. This claim is allowable at least for the reasons provided above with respect to claim 22.

Claim 33 recites “a plate having a general triangular shape, said plate having an upper hole near an upper vertex through which a screw is passed for securing said plate to the L5 vertebra, and a pair of lower holes situated near respective ones of first and second lower vertices of said plate, each of said pair of lower holes having a screw passed therethrough to secure said plate to the S1 vertebra, wherein said plate includes a profile between said upper vertex and said first and second lower vertices adapted to conform to the anterior margin of at least one of the L5 and S1 vertebrae.” As discussed above with respect to claim 1, Jobe does not expressly or inherently disclose a plate for anterior placement on L5-S1. Thus, the arrangement of elements as recited in claim 33 is neither expressly nor inherently disclosed in Jobe, and withdrawal of the rejection of claim 33 is respectfully requested.

Claims 34, 37, 40, and 46 depend from claim 33 and were also rejected as being anticipated by Jobe. These claims are allowable at least for the reasons provided above with respect to claim 33, and also for other reasons. For example, claim 34 recites that the plate includes “a posterior face having a protrusion extending along at least part of the width” of the plate. Jobe, on the other hand, only discloses flange or rib 30 extending along the length of the plate between the adjacent bone segments. The significance of the protrusion extending along at least part of the width is that the protrusion can support a portion of the axial load being transferred between L5 and S1. This distinction with the longitudinal rib of Jobe is significant because the rib cannot support axial loads since it extends along the axis of or transversely to the width of the plate. Claim 37 recites “wherein said plate includes a posterior face having an edge about said plate, said posterior face including an anchoring point extending therefrom adjacent said upper vertex” in addition to the hole for the screw recited in claim 33. There is no disclosure in Jobe of both a post/screw and an anchoring point near the upper vertex of the plate. Jobe also fails to disclose the means for blocking screws recited in claim 46 that includes “a retaining element which can be screwed onto the plate.” The Office Action points to Figure 5 as disclosing such a feature, but a review of the specification and Figure 5 does not reveal any structure that is screwed onto the plate that functions as the means for blocking.

Claims 2, 4-6, 8-9, 12, 20, 25, 38, 39, 41, 43, 48, 67-68, 71-73, 75 and 78 were rejected as being unpatentable over Jobe in view of U.S. Patent No. 6,306,139 to Fuentes. Fuentes would potentially qualify as prior art under 35 USC §102(e). Applicants reserve the right to swear behind the filing date of Fuentes with an affidavit under 37 CFR §1.131 in this application or in any continuing application.

With regard to claims 67-68, 71-73, 75 and 78, as discussed above, claim 67 is an independent claim and is allowable since it presents original allowable claim 45 in independent form. Furthermore, the Final Office Action has not applied any reference to claim 67, so it is not clear from the record what the basis for rejecting claim 67 is. Claims 68, 71-73, 75 and 78 depend from claim 67 and are allowable at least because claim 67 is allowable. Accordingly, withdrawal of the rejection of these claims is respectfully requested.

With regard to claim 20, as discussed above, it depends from base claim 14, which was indicated as allowable. Accordingly, it is not clear how claim 20 can be obvious in view of the combination of Jobe and Fuentes when claim 14 is allowable.

Assuming for the purposes of this response only that Fuentes were prior art, the combination of Jobe and Fuentes does not suggest the features of the remaining claims 2, 4-6, 8-9, 12, 25, 38, 39, 41, 43 and 48. Claims 2, 4-6, 8-9 and 12 depend from claim 1, and are allowable at least because claim 1 is allowable for the reasons provided above and for other reasons. For example, for claim 5 the Office Action correctly points out that the inferior margin of the L5 vertebrae is not being claimed. What is being claimed in claim 5, however, is “a protrusion extending from said posterior face” adapted to contact the inferior margin of the L5 vertebra. Neither Jobe nor Fuentes disclose or suggest this feature since, as discussed above, Jobe only disclose flange or rib 30 that extends longitudinally along the axis of the plate. Such a longitudinal flange or rib is not adapted to contact the inferior margin of a vertebra. With regard to claim 6, it recites that the “lower nodes each have a thickened portion adapted to conform to the profile of the anterior face of the S1 vertebra.” Fuentes may generally disclose modifying a thickness of the plate, but there is no disclosure or suggestion of providing lower nodes of a triangular plate with thickened portions as claimed in claim 6.

Claim 25 depends from claim 22, and is allowable at least for the reasons that claim 22 is allowable as provided above. Claims 38, 41, 43 and 48 depend from claim 33, and are allowable at least for the reasons that claim 33 is allowable as provided above.

Claim 39 depends from claim 23 and was rejected as being unpatentable over Jobe in view of Fuentes. Claim 39 recites that “said pair of lower holes have an oblong shape extending in the direction toward said vertex.” As discussed in Applicants’ specification on page 11, first paragraph, the oblong holes provide freedom for locating screws in S1 and allow post-implantation adaptation to patient morphology. The features recited in claim 39 are thus not merely a design choice, and are not suggested in either Jobe or Fuentes. To establish a prima facie case of obviousness, there must be some reason, suggestion or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. It is submitted that neither Jobe nor Fuentes contains the required reason, suggestion or motivation to modify the device in Jobe as set forth in the Office Action.

In the Response to Arguments section of the Office Action response, it was asserted that oblong holes are commonly used in plates to “provide freedom for locating screws” and to “allow post-implantation adaptation to patient morphology”. To support this assertion, U.S. Patent No. 6,652,525 to Assaker et al. was cited as having oblong opening 9. Assaker discloses hole 9 that is located in the middle of the plate in Assaker, and is aligned with a bone graft positioned between vertebra, while the upper and lower pairs of circular holes are aligned with upper and lower vertebrae, respectively. The oblong hole 9 in Assaker et al. does not align with either of the vertebrae. Since hole 9 does not receive screws for engagement to vertebrae, Assaker does not provide the disclosure or suggestion necessary to modify the combination of Jobe and Fuentes to arrive at claim 39.

It appears that the quoted language in the Office Action regarding the motivation or suggestion to modify the combination of Jobe and Fuentes to arrive at claim 39 is extracted from Applicants’ own specification rather than from the prior. It is not permissible to use Applicants’ own disclosure to supply the motivation or suggest to

modify the prior art. *See In re Dow Chem. Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) (both the suggestion and reasonable expectation of success must be found in the prior art, and not in the applicant's disclosure.) Furthermore, the Office Action states that "this feature alone does not make the invention patentably distinct." In response, it is submitted that this feature is not being claimed alone, but in combination with other features recited in claim 33. Thus, the combination of Jobe and Fuentes do not disclose or suggest the recited combination of features in claim 39 since it has not been established that the reason or motivation for modifying Jobe and Fuentes is found in the prior art.

Claims 10, 11, 18, 19, 23, 42, 47, 74 and 77 were also rejected as being unpatentable over Jobe in view of Fuentes. With regard to claims 74 and 77, as discussed above claim 67 is an independent claim and is allowable since it presents original allowable claim 45 in independent form. Claims 74 and 77 depend from claim 67 and are allowable at least because claim 67 is allowable. Accordingly, withdrawal of the rejection of these claims is respectfully requested.

With regard to claims 18 and 19, as discussed above these claims depend from base claim 14, which was indicated as allowable. Accordingly, it is not clear how claims 18 and 19 can be obvious in view of the combination of Jobe and Fuentes when claim 14 is allowable.

With regard to the remaining claims 10, 11 23, 42 and 47, the Office Action asserts that "it would have been an obvious matter of design choice to make the retaining element with a triangular or circular shape, since such modification would have involved mere change in the shape of a component." To establish a prima facie case of obviousness, there must be some reason, suggestion or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. As admitted in the Office Action, the references do not disclose circular or triangular retaining elements.

With regard to claim 11 and 42, Fuentes does not disclose or suggest a retaining element with a circular shape. In the Response to Arguments section, it is asserted that it "is obvious that the retaining element disclosed by Fuentes may also be a circular

shape....” However, this conclusion is not supported with reference to any teaching in the prior art in support of it. A change in shape of a component is not a matter of obvious design choice if the prior art teaches away from the shape, or if the change in shape would render the prior inoperable for its intended purpose. Fuentes teaches away from providing circular retaining elements since it discloses an anti-extraction device that is rotated about its axis from a first position for screw insertion to a second position that obturates access to the screw holes. A circular anti-extraction device sized to block the screw holes could not be rotated about its axis between blocking and unblocking positions relative to the plate holes since a circular device would occupy the same area of the plate at every rotated position of the retaining element. Accordingly, there would be no unblocked position to allow screw insertion. If the anti-extraction device in Fuentes were circular, then Fuentes would be inoperable for its intended purpose, to allow screw insertion with the anti-extraction device attached to the plate. Thus, the combination of Jobe and Fuentes fails to teach or suggest a circular retaining element as recited in claims 11 and 42.

With regard to claims 10, 23, and 47 directed to a triangular retaining element, the retaining element as claimed has the same shape as the plate, allowing the dimensions of the plate and thus intrusion into the adjacent anatomy by the plate to be minimized while providing screw retention. The combination of Jobe and Fuentes fails to teach or suggest a retaining element with a geometry that matches the plate geometry. In contrast, the anti-extraction device in Fuentes is X-shaped, while the plate has a rectangular shape. The anti-extraction device in Fuentes includes a profile that is minimized relative to the plate to facilitate screw insertion which the anti-extraction device is attached to the plate. Accordingly, Fuentes fails to supply any suggestion or motivation to provide a triangular retaining element and a triangular plate, and claims 10, 23 and 47 are allowable.

Claim 28 was rejected as being unpatentable over U.S. Patent No. 6,045,552 to Zucherman et al in view of Jobe. In the previous Office Action response, arguments were presented by the Applicants that the prima facie case of obviousness had not been established. No response to these arguments have been provided in the Final Office Action. As discussed in the previous response, claim 28 is a method claim and recites

“installing a generally triangular-shaped plate having an upper node along the face of the L5 vertebra and a pair of lower nodes along the anterior face of the S1 vertebra....”

Zucherman discloses a plate positionable on the anterior face of the L5-S1 vertebrae with keels extending from the lower surface of the plate and into the L5 and S1 vertebrae. In Fig. 2 of Zucherman, the plate has a lower, triangular shaped end portion with the pointed end of the triangular portion oriented downwardly along S1. The Office Action asserts that Jobe discloses a triangular-shaped plate “capable” of being positioned along the anterior face of the S1 vertebra. As discussed above with respect to claim 1, Jobe does not disclose, either inherently or expressly, that the plate is capable of being anteriorly positioned on S1 or for use in such vertebral stabilization procedures. Accordingly, one skilled in the art would not look to the teaching of Jobe to modify Zucherman since Jobe does not provide any suggest or motivation for making the modification to a spinal plate for anterior placement on L5-S1.

Furthermore, Jobe is silent as to any particular orientation it might have relative to the bone segments. Contrary to the assertion in the Office Action, Jobe does not disclose “upper and lower nodes” since the orientation of the plate in Jobe is irrelevant so long as the plate extends across the fracture line between the bone segments. Accordingly, even if they were properly combinable, the combination of Zucherman and Jobe would, at most, suggest orienting the single node of the triangular plate downwardly along S1. The combination of Zucherman and Jobe cannot render claim 28 unpatentable, and withdrawal of the rejection of the same is respectfully requested.

Claims 29-32 were rejected as being unpatentable over Zucherman et al. in view of Jobe as applied to claim 28, and further in view of Fuentes. Claims 29 –32 depend from claim 28 and are allowable at least for the reasons claim 28 is allowable.

Claims 35-36 and 69-70 were rejected as being unpatentable over Jobe as applied to claim 33, and further in view of Zucherman. With regard to claims 69 and 70, as discussed above claim 67 is an independent claim and is allowable since it presents original allowable claim 45 in independent form. Claims 69 and 70 depend from claim 67 and are allowable at least because claim 67 is allowable. Accordingly, withdrawal of the rejection of these claims is respectfully requested.

Claims 35 and 36 depend from claim 33, and are allowable at least for the reasons claim 33 is allowable as discussed above.

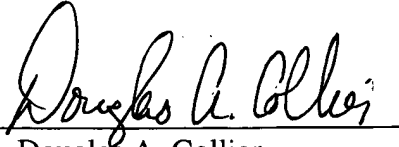
Claims 49 and 50 were rejected as being unpatentable over Zucherman in view of Jobe. Zucherman discloses a plate positionable on the anterior face of the L5-S1 vertebrae with keels extending from the lower surface of the plate and into the L5 and S1 vertebrae. In Fig. 2 of Zucherman, the plate has a lower, triangular shaped end portion with the pointed end of the triangular portion oriented downwardly along S1 as discussed above with respect to claim 28. Jobe does not provide any teaching or suggestion regarding any particular orientation of the triangular plate disclosed therein, only that the plate extends across the fracture line between the bone segments. Accordingly, the combination of Zucherman and Jobe would, at most, suggest orienting the single node of the triangular plate downwardly along S1. In contrast, claim 49 recites “a plate having a triangular shape, said plate having an upper vertex positionable over L5 and lower vertices positionable over S1, each of said vertices having a hole formed therethrough; three screws, each of said screws positioned through a corresponding one of said holes to secure said plate to L5 and S1.” Accordingly, one skilled in the art would not look to the teaching of Jobe to modify Zucherman since Jobe does not provide any suggest or motivation for making the modification to a spinal plate for anterior placement on L5-S1.

In the Response to Arguments section of the Final Office Action, it was asserted that the location of the intended use of the invention also does not make the invention patentably distinct. However, it is respectfully submitted that claim 49 requires a plate having structure that allows the upper vertex to be positionable over L5 and the lower vertices positionable over S1. There is no disclosure or suggestion in Zucherman and Jobe of a plate having such a structure. Accordingly, claim 49 is allowable and withdrawal of the rejection of the same is respectfully requested.

In view of the foregoing remarks, reconsideration of the present application as amended is respectfully requested. These amendments and remarks do not introduce new matter or limit the scope of coverage available under the doctrine of equivalents. Action towards a notice of allowance for this application, including claims 1-88 is hereby

solicited. The undersigned would welcome an interview with the Examiner to resolve any outstanding issues that might arise with respect to the present application.

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